DETAILED ACTION

Responsive to communication entered 04/06/2011.

Status of Claims

Claims 1-9 and 15-20 are canceled. Claims 10-12 and 14 are amended, and Claims 21-30 are added as set forth in the Applicant's Reply filed 04/06/2011. Claims 10-14 and 21-30 are examined.

Priority

The instant application, 10/590,785, Publication No. US 2010/0143933, is a national stage entry of PCT/JP2005/003135, filed on 02/25/2005, which claims foreign priority to Japanese Patent Application 2004-051184, filed on 02/26/2004.

Withdrawn Objections/Rejections

I. The rejection of Claim 19 under 35 U.S.C. 101 is withdrawn in view of Applicant's cancellation of the claim.

II. The rejection of Claims 2, 3, 4, 7, 15, 17 and 19 under 35 U.S.C. 112, second paragraph, is withdrawn in view of Applicant's cancellation of the claims.

III. The rejection of Claims 1-20 under 35 U.S.C. 102(a) as being anticipated by Wada *et al.*, WO 2004/092733, filed on April 4, 2004; published on October 28, 2004 (IDS submitted on 03/14/2008) is withdrawn in view of Applicant's argument, amendment and cancellation of the claims.

IV. The rejection of Claims 1-9 and 15-20 under 35 U.S.C. 102(b) as being anticipated by Moghaddam *et al.*, U.S. Patent 5,972,718, issued on October 26, 1999 (of record) is withdrawn in view of Applicant's cancellation of the claims.

V. The rejection of Claims 1-8, 16 and 19-20 under 35 U.S.C. 102(b) as being anticipated by Senn *et al.,* WO 91/10747, published on July 25, 1991 (of record) is withdrawn in view of Applicant's argument, amendment and cancellation of the claims.

VI. The rejection of Claims 1-8, 10-13, and 19-20 under 35 U.S.C. 102(b) as being anticipated by Bloch *et al.,* WO 90/02202, published on March 8, 1990 (of record) is withdrawn in view of Applicant's argument, amendment and cancellation of the claims.

VII. The rejection of Claims 1-9 under 35 U.S.C. 102(f) is withdrawn in view of Applicant's cancellation of the claims.

VIII. The rejection of Claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over Mutsumi *et al.* JP 2003-149244 (IDS entered 01/12/2007) in view of Fluka Catalog 1999/2000, pages 1115, 1132 (of record) is withdrawn in view of Applicant's argument, amendment and cancellation of the claims.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14 and 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This new rejection is necessitated by Applicant's amendments to the claims.

Claim 10 recites "An immunoagglutination immunoassay for inhibiting decrease in measured values in immunoassays." It is not clear how recitation "an

immunoagglutination immunoassay" can be used and/or connected with recitation "for inhibiting decrease in measured values in immunoassays."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States;

Claims 10-14 and 21-30 are rejected under 35 U.S.C. 102(b) as being anticipated by **Moghaddam** *et al.*, U.S. Patent 5,972,718, issued on October 26, 1999 (of record).

This rejection is maintained from the previous Office action.

Claims 10-14 and 21-30, as recited in independent Claim 10, are drawn to "An immunoagglutination immunoassay for inhibiting decrease in measured values in immunoassays, comprising: mixing a test sample with an agent for inhibiting decrease in measured values in immunoagglutination immunoassays, caused by an interfering substance(s), which agent is an ionic surfactant having a molecular weight of 1000 to 100,000, said ionic surfactant being a polymer in which a hydrophobic cyclic monomer(s) having an ionic functional group(s) is(are) polymerized to form a mixture of said test sample and said agent.

Moghaddam *et al.*, throughout the publication, and, for example, in Claim 1, teach a method of detecting heparin-induced antibodies in blood plasma or serum to screen for heparin-induced thrombocytopenia using a linear, non-glycosaminoglycan polymer having a backbone and carrying negative charges distributed along the polymer chain, wherein the polymer is between 2-6,000 Daltons in molecular mass and wherein the polymer is selected from the group consisting of polyvinyl sulfonate, polystyrene sulfonate, polyanetholesulfonate, polyvinyl phosphate, polyvinyl phosphonate and polyvinyl sulfate. Shown at Fig. 6 and 7, Moghaddam *et al.* teach use the different amounts of polystyrene sulfonate or polyanetholesulfonate in the assays. Moghaddam *et al.* teach an immunoagglutination method by disclosing the use of latex particles in detecting ability of HITP antibodies to promote agglutination. Column 11, lines 57-62. Moghaddam *et al.* teach that diagnostic applications may be implemented in the form of a kit containing complexes which undergo a reaction with a sample of a patient's blood. Column 11, line 65 through Column 12, line 10.

According to MPEP 2131.02, the prior art species, polystyrene sulfonate or polyanethole sulfonate, taught by Moghaddam *et al.,* will anticipate the agent for inhibiting decrease in measured values in immunoassays of the instant Claims 10-14 and 21-30.

"A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus." The species in that case will anticipate the genus. *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960).

As to recitation "0.01% to 5% (weight/volume)" of Claim 14, a specific example in the prior art (See Fig. 6 and 7 of the Moghaddam *et al.* reference), which is within a claimed range, anticipates the range. MPEP 2131.01.

"[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated' if *one* of them is in the prior art." Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing In re Petering, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original).

Therefore, each and every element of the claims is met by the Moghaddam *et al.* reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-14 and 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mitsuhiro** *et al.* JP 09-304384 (IDS entered 01/12/2007) in view of

either **Wada** *et al.*, WO 2004/092733, filed on April 4, 2004; published on October 28, 2004 (IDS submitted on 03/14/2008) or **Senn** *et al.,* WO 91/10747, published on July 25, 1991 (of record), each taken separately.

This new rejection is necessitated by Applicant's amendments to the claims.

Mitsuhiro *et al.,* throughout the publication, and, for example, in paragraphs [0004], [0010] and [0011], teach the use of a conjugated diene polymer having sulfonic groups, such as, for example, sodium polystyrene sulfonate, which is an ionic surfactant, with average molecular weight of 3,000 or more, for inhibiting a nonspecific ligation reaction in an antigen-antibody reaction in immunoassays including a latex agglutination assay.

Mitsuhiro *et al.* do not teach the use of an ionic surfactant as an agent for inhibiting decrease in measured values in immunoassays.

Wada *et al.*, throughout the publication, and, for example, at page 6, lines 6-11; page 16, lines 6-23; page 19, lines 21-33; page 21, lines 14-16, teach use of a polyanionic or polycationic charged polymer in methods and compositions for detecting or identifying an analyte of interest in a biological sample, such as serum, plasma, a whole blood, by contacting the sample containing the analyte with one or more affinity molecule to form a complex of the analyte and the one or more affinity molecule, which affinity molecule can be an antibody, wherein the charged polymer reduces the sample constituent interference with separation of, e. g., a complex of an analyte and an affinity molecule from any free (e. g., unbound) affinity molecule, particularly separation of a complex of an analyte and a conjugate of an affinity molecule and a charged carrier

molecule from any free (e. g., unbound) conjugate, which makes it possible to sensitively and specifically detect or identify the analyte of interest in a sample. At page 19, lines 8-11, Wada *et al*. teach that, when the charged polymer is present in the contacting step of the sample containing the objective substance with the affinity substance for forming the complex, the concentration of the charged polymer present in the solution (e. g., buffer) may be variable depending on the kind of the charged polymer to be used. At page 19, lines 11-13, Wada *et al*. teach that, generally, the concentration of the charged polymer may be any concentration at which the presence of the charged polymer can reduce the interference without affecting any interaction between the analyte and the affinity substance. At page 19, lines 5-7, Claims 31-34, Wada *et al*. teach the concentration of the charged polymer to be usually between about 0.01 to 5% (w/v), preferably about 0.05 to 2% (w/v), more preferably about 0.5 to 1.5 % (w/v), for example about 1% (w/v). At page 26, lines 6-9, Wada *et al*. teach that a sample containing the analyte can be contacted with an affinity molecule/charged carrier molecule conjugate to form a complex of the analyte and the conjugate, and the resulting complex can be separated from any unbound conjugate in the presence of a charged polymer. At page 27, lines 19-23, Wada *et al*. teach that the charged carrier molecules can be synthetic macromolecular compounds such as polystyrene latex, styrene-butadiene copolymer, styrene-methacrylate copolymer, acrolein-ethylene glycol dimethacrylate copolymer, styrene-styrenesulfonate latex, polyacrylamide, polyglycidyl methacrylate, polyacrolein-coated particles, etc. At page 16, lines 6-12, Claims 2 and 4, Wada *et al*. teach that the charged polymer can be, e. g., polyanethole sulfonic acid.

Senn *et al.,* throughout the publication, and, for example, at page 2, lines 4-6; page 12, lines 1-9 and lines 23-24, teach use of polyanionic, in particular polysulfated or polysulfonated (i.e. exhibiting -SO_3" groups) polymers, including polyanethole sulfonate, for reducing non-specific binding and increasing the specificity as well as the sensitivity of the testing for anti-HIV antibodies in neat (undiluted samples) from the biological fluids such as blood, plasma and serum. At page 12, lines 10-22, Senn *et al.* teach that, in order to have a good test, when using the polyanionic polymer, normal optimization with respect to type, molecular weight, substitution degree etc. shall therefore always take place. For instance, for an anti-HIV antibody test the concentration of the polymer, such as dextran sulfate, is recommended by Senn *et al.* to be within 0.01-0.14% (w/w). Senn *et al.* teach that in many cases the upper limit of the polymer concentration should be lowered down to 0.10%.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to have made and used the charged polymers reducing the sample constituent interference, as taught by Wada *et al.* or Senn *et al.,* in a latex agglutination assay, taught by Mitsuhiro *et al.*

One of ordinary skill in the art would have been motivated to have made and used the charged polymers reducing the sample constituent interference, as taught by Wada *et al.* or Senn *et al.,* in latex agglutination assay, taught by Mitsuhiro *et al.*, because it would be desirable to reduce the influence by interfering substances in test samples to promote the accuracy of the immunoassays.

One of ordinary skill in the art would have had a reasonable expectation of success in making and using the charged polymers reducing the sample constituent interference, as taught by Wada *et al.* or Senn *et al.,* in latex agglutination assay, taught by Mitsuhiro *et al.*, because the use of sulfonate-based polymeric surface active agents for reducing the influence by interfering substances in test samples to promote the accuracy of immunoassays was known in the art, as taught by Wada *et al.* or Senn *et al.*

Response to Arguments

Applicant's arguments filed on 04/06/2011 with regard to the rejection of Claims 10-14 under 35 U.S.C. 102(b) as being anticipated by Moghaddam *et al.*, U.S. Patent 5,972,718, issued on October 26, 1999 (of record) have been fully considered but they are not persuasive. Applicant traversed Moghaddam *et al.* for not teaching an immunoassay wherein the particles are coated with antigen or antibody, and the polymer surfactant is not coated on the particles. Contrary to Applicants' allegation, Moghaddam *et al.*, provide the required teachings as follows:

"Other methods are suitable for the detection of HITP antibodies bound to synthetic polymer/PF4 complexes. In one method, red blood cells (or other particles) are coated with polyclonal or monoclonal antibodies specific for human IgG, IgM, or IgA (Y. Shibata, et al., Vox Sang 41:25-31, 1981). Adhesion of these red cells to complexes consisting of HITP antibody bound to immobilized synthetic polymer/PF4 complexes is then utilized to indicate the presence of bound HITP antibody." See Col. 11, lines 48-56.

Accordingly, the claim rejection under 35 U.S.C. 102(b) as being anticipated by Moghaddam *et al.* is maintained.

Conclusion

Claims 10-14 and 21-30 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GALINA YAKOVLEVA whose telephone number is (571)270-3282. The examiner can normally be reached on Monday-Friday 8:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. Y./
Examiner, Art Unit 1641

/Shafiqul Haq/
Primary Examiner, Art Unit 1641